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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,294	09/29/2003	Thomas L. Cantor	532212001900	5531

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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

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06/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,294	CANTOR ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8 and 10-24* is/are pending in the application.

4a) Of the above claim(s) *16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8 and 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 5/18/2007 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 6-7 and 9 are cancelled.

2. Claims 1-5, 8, 10-15 are under examination. Claims 16-24 are withdrawn from further consideration.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-3, 8, 10-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al. in view of Holthuis et al..

Gao et al. teach a parathyorid hormone (PTH) assay control. The assay comprises a whole PTH component having amino acid 1-84 of PTH, and a PTH fragment having amino acid 7-84 of PTH which falls within the recited range, i.e. spanning position 2 throuigh 33 of PTH of its N-terminal, and C-terminal spanning from 35 through position of 84 of PTH, where Gao et al. teach storing the PTH in lyophilized form, e.g. protein matrix base (See page 606, right column, Materials and Methods- Chemicals and Reagents). The ratio of the whole PTH to the 7-84 PTH fragment is within range about 1% to 99% (See Figure 2). Gao et al. also teach using serum (e.g. protein matrix) and lyophilzation method for the storage of the whole PTH (1-84) (See Chemical and Reagent). However, Gao et al. do not explicitly teach treating the other PTH fragments with the serum and lypholization for storage.

Holthuis et al. teach using serum albumin as protein matrix base and lyophilization for storage of PTH. The advantages include, for the increase storage life of PTH, serving as carrier, for reconstruction and enhance absorption (Col. 1, line 35-55).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Gao et al. with the serum and lyophilization process as taught by Holthuis et al. to treat the PTH fragments in order to increase stability of storage and enhance the reconstruction of the PTH fragment for assay.

With respect to claim 2 and 14-15, Gao et al. teach comparing the binding assay of IRMA and conventional Nichols assay by mixing the whole PTH component with the PTH fragment in a predetermined ratio (See Figure 2).

With respect to claim 3, Gao et al. using synthetic method to generate the PTH components. Supra.

With respect to claims 6-8, Gao et al. teach using lyophilized form for storage of the PTH components to prolong storage life of the PTH peptides. Surpa.

With respect to claims 9-10, Gao et al. established that there is no cross-reactivity of whole PTH with the 7-84 PTH fragment by detecting binding of these two peptides in different ration (See Figure 2).

With respect to claims 11 and 13, Tthe recitation of "instructions" is not afforded patentable weight because the recited "instructions" are not functionally related to the underlying kit, but merely teach a new use for an existing product. In re Ngai, 70 USPQ2d 1862 (CAFC 2004).

4. Claims 1-5, 11-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Bouillon et al. in view of Holthuis et al..

Bouillon et al. teach a parathyorid hormone (PTH) assay control. The assay comprises a whole PTH component having amino acid 1-84 of PTH, and a PTH fragment having amino acid 23-84 of PTH which falls within the recited range, i.e. spanning position 2 throuigh 33 of PTH of its N-terminal, and C-terminal spanning from 35 through position of 84 of PTH (See page 271, right column, Materials and Methods-Reagents). The ratio of the whole PTH and the 23-84 PTH fragment is also within the range from 1-99%. Supra. However, Bouillon et al. do not explicitly teach using protein matrix base and lyophilization for storage of PTH.

Holthuis et al. teach using serum albumin as protein matrix base and lyophilization for storage of PTH. The advantages include, for the increase storage life of PTH, serving as carrier, for reconstruction and enhance absorption (Col. 1, line 35-55).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Bouillon et al. with the protein matrix serum and lyophilization as taught by Holthuis et al. in order to increase the storage life of the PTH peptides and reconstruction for subsequent analysis.

With respect to claim 2 and 14-15, Bouillon et al. teach comparing interferring effects of PTH fragments by mixing the whole PTH component with the PTH fragment in a predetermined ratio, e.g. excess of 1000 fold molar ratio (See page 273, right column, second paragraph).

With respect to claim 3, Buillon et al. using synthetic method to generate the PTH components. Supra.

With respect to claims 4-5, Bouillon et al. teach purifying PTH from natural sources, such as human hPTH by chromatography (See page 272, left column, second paragraph). Although Bouillon et al. teach isolate and purify hPTH (52-84), which does not fall within the recited amino acid residue range, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Bouillon et al. to isolate 7-84 or 23-84 PTH since using chromatograph of isolating peptide of interest is a routine practice in the field, and a matter of time/cost consideration comparing chemical synthesis of peptide.

With respect to claims 11 and 13, Tthe recitation of "instructions" is not afforded patentable weight because the recited "instructions" are not functionally related to the underlying kit, but merely teach a new use for an existing product. In re Ngai, 70 USPQ2d 1862 (CAFC 2004).

Response to Applicant's Response

5. Applicant's arguments with respect to claims 1-5, 8, 10-15 have been considered but are moot in view of the new ground(s) of rejection.

Gao et al. reference

During the interview with applicant's representative, Mr. Smith, on 5/7/2007, applicant points out that Gao et al. reference does not teach using one composition, rather Gao et al. using separate controls, e.g. whole PTH and PTH fragments. Furthermore, applicant stressed that Gao et al. teaches using serum and lyophilization to only whole PTH (1-84). There is no disclosure that Gao et al. treat the PTH fragments with serum and lyophilization. Therefore Gao et al. do not anticipate the instant invention. Examiner already issues a new ground of rejection in this Office Action (See above). Examiner would also like to clarify the Office position.

The instant invention is drawn to an assay control of PTH. The control comprises two peptides, one is the whole PTH, and the other is the PTH fragments with certain positions as recited in the claim 1. Furthermore, these peptides have protein matrix and are lyophilized. The above prior art, particularly Gao et al. reference has all the features except the PTH fragments lyophilized and serum treated.

Since the current application is a product claim, MPEP §2112 states "[Where] the claimed and prior art products are identical or substantially identical in *structure or composition*, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)(emphasis added). With respect to the two main peptides used in this invention, Gao et al. also teaches using the recited peptides. Thus the whole PTH and PTH fragments taught by Gao et al. can also perform the control assay as recited in the instant claim. With respect to the usage of protein matrix, such as serum, and lyophilization method for storage, examiner has provide a secondary reference Holthius et al. where the usage of serum and lyophilization is well-known and widely practiced in the art to preserve stability of PTH and for better reconstruction.

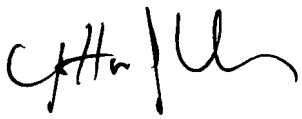
Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jacob Cheu
Examiner
Art Unit 1641

June 10, 2007